



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2014-F-0364]

Food Additives Permitted for Direct Addition to Food for Human Consumption; TBHQ

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations by removing the upper bound of the melting point range in the regulation for the antioxidant tertiary butylhydroquinone (TBHQ) and adding a purity acceptance criterion. This action is in response to a petition submitted by Eastman Chemical Company.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Director of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA-2014-F-0364, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2014-F-0364 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1309.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register on April 8, 2014 (79 FR 19301), we announced that we filed a food additive petition (FAP 4A4803) submitted by Eastman Chemical Company, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001 (petitioner). The petition proposed to amend the food additive regulations in § 172.185 (21 CFR 172.185) TBHQ by removing the upper bound of the specified melting point range (126.5 °C to 128.5 °C) and by adding an acceptance criterion to measure purity of the additive. Specifically, the petition proposed to allow the use of TBHQ with a melting point that is 126.5 °C or higher. In addition to this change in melting point specification, the petition also proposed to add an acceptance criterion for purity of not less than 99.0 percent TBHQ, as tested by the titration assay specified in the most current edition of the Food Chemicals Codex (FCC).

TBHQ is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948-33-0). In the Federal Register of November 30, 1972 (37 FR 25356), we issued a final rule that was codified in 21 CFR 121.1244 to provide for the safe use of TBHQ in food under certain conditions, including a melting point range for TBHQ of 126.5 °C – 128.5 °C. An amendment to § 121.1244 was issued in the Federal Register of December 10, 1976 (41 FR 53981) to recognize the name “TBHQ” as the common name for tertiary butylhydroquinone, and to add the Chemical Abstracts Service Registry Number and nomenclature in the introductory text of § 121.1244. In the Federal Register of March 15, 1977 (42 FR 14302 at 14495), TBHQ was recodified from § 121.1244 to § 172.185. No amendments to the TBHQ regulation have been made since then.

II. Evaluation of Petition

The melting point range of 126.5 °C – 128.5 °C was originally included by FDA in the regulation for TBHQ as part of the chemical identity of the additive and to ensure purity. The

melting point range describes the initial and final temperatures at which the substance melts. Data provided in the subject petition show that TBHQ with an initial melting point of 126.5 °C has a purity of not less than 99 percent, which is consistent with the petitioner's proposed acceptance criterion specification. However, according to the petitioner, analytical and manufacturing variability can result in batches of TBHQ that have a final melting point greater than 128.5 °C, but are of suitably high purity. Using the titration assay for TBHQ in the FCC 9th Edition (the most current edition), the petitioner analyzed multiple samples of TBHQ with a final melting point above 128.5 °C. All samples had a purity of at least 99 percent. Based on their analysis of these data, the petitioner concluded that, while melting point has utility in identifying TBHQ, a maximum melting point specification limit is unnecessary in the regulation to ensure purity. We agree with the petitioner and have concluded that the data provided support their request to remove the upper bound of the melting point range specified in §172.185(a), and add a purity acceptance criterion of not less than 99 percent determined using the titration assay for TBHQ in the FCC 9th Edition or an equivalent method (Ref. 1).

The petitioner did not propose any modifications to the use or intended technical effect of TBHQ as currently permitted in § 172.185. As such, the petitioner's proposed amendments will have no impact on dietary exposure of TBHQ. Therefore, we did not reevaluate the dietary exposure to TBHQ (Ref. 1). The petitioner also stated that there are no changes to the manufacturing process and therefore no new components will be introduced into the diet.

No new toxicology studies were submitted in support of the safety of the petition request. The petitioner referenced the toxicological data that had been previously submitted and evaluated when the regulation for TBHQ was first issued (37 FR 25356). As part of the safety evaluation for this petition, we conducted an updated literature search for new toxicological studies related

to the safety of TBHQ. Our literature search did not reveal any new safety issues with the regulated use of TBHQ or any safety concerns regarding TBHQ with a final melting point in excess of 128.5 °C (Ref. 2).

III. Incorporation by Reference

FDA is incorporating by reference the monograph for TBHQ in the FCC 9th edition (the most current edition), which was approved by the Office of the Federal Register. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD, 20852, 1-800-227-8772, <http://www.usp.org/>.

The FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients. The FCC monograph for TBHQ contains a description of a titration assay, which is an analytical method used to determine the purity of TBHQ.

IV. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the proposed amendments to remove the upper bound of the melting point range in the regulation for TBHQ and to add a purity acceptance criterion are safe and appropriate. Therefore, we are amending the regulations in 21 CFR part 172 as set forth in this document.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Environmental Impact

We have considered the environmental effects of this rule. As stated in the April 8, 2014, Federal Register notice of petition for FAP 4A4803 (79 FR 19301), we have determined, under 21 CFR 25.30(i), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect that determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response

to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. Section 301(II) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(II) of the FD&C Act (21 U.S.C. 331(II)). Section 301(II) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(II)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(II) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(II) of the FD&C Act applies.

X. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4

p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. FDA Memorandum from H. Lee, to E. Anderson, June 18, 2014.
2. FDA Memorandum from A. Khan to E. Anderson, August 6, 2014.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Amend § 172.185 as follows:

- a. Revise paragraph (a);
- b. Redesignate paragraphs (b) and (c) as paragraphs (c) and (d), respectively; and
- c. Add new paragraph (b).

The revision and addition read as follows:

§ 172.185 TBHQ.

* * * * *

- (a) The food additive has a melting point of not less than 126.5 °C.
- (b) The percentage of TBHQ in the food additive is not less than 99.0 percent when tested by the assay described in the Food Chemicals Codex, 9th ed. (2014), pp. 1192-1194, which is incorporated by reference, or an equivalent method. The Director of the Office of the

Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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Dated: June 9, 2015.

Susan Bernard,

Director,

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

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